

REMARKS

In the Office Action, claims 34-38 are rejected under 35 U.S.C. § 112, second paragraph; claims 1, 3-8, 10, 11, 15, 17, 20-23 and 25-38 are rejected under 35 U.S.C. § 102; and claims 2, 9, 12-14, 16, 18, 19, 24 and 26-38 are rejected under 35 U.S.C. § 103. Applicants believe that the rejections are improper based on at least the reasons set forth below.

In the Office Action, claims 34-38 are rejected under 35 U.S.C. § 112, second paragraph. The Patent Office alleges that claims 34-38 are unclear as the claims only recite a method of detection and control, but are directed to a method of providing dialysis therapy.

Applicants believe that this rejection is improper. Of claims 34-38, claim 34 is the sole independent claim. Claim 34 recites a method of providing dialysis therapy. The method includes providing an ammonia sensor that includes a sensing membrane. The sensing membrane has a hydrophobic membrane layer composed of a fluorine-containing polymeric compound and a pH sensitive dye embedded within a porous structure of the hydrophobic membrane layer wherein the ammonia sensor is capable of colorimetrically detecting ammonia dissolved in a dialysis solution. The method also at least includes the selective detection of an amount of the ammonia with the ammonia sensor. As fully supported in the specification, the ammonia sensing membranes of the present invention can be adapted for use, such as during dialysis therapy, in a variety of different and suitable ways including, for example, as a total ammonia and ammonium sensor. See, Specification, page 18, lines 3-9. Thus, one skilled in the art should readily understand that the selective detection of ammonia with the ammonia sensor is one aspect of the claimed method of providing dialysis therapy as required by claim 34. Claims 35-38 depend from claim 34 and thus, as a matter of law, incorporate each of the features therein. Therefore, Applicants believe that claims 34-38 fully comply with 35 U.S.C. § 112, second paragraph.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, claims 1, 3-8, 10, 11, 15, 17 and 20-23 are rejected under 35 U.S.C. § 102 in view of EP 1037045 ("EP 045"). The Patent Office essentially asserts that the EP 045 reference teaches the claimed invention. Applicants believe that this rejection is improper.

Of the pending claims at issue, claims 1, 8 and 15 are the sole independent claims. Claim 1 recites a membrane that is capable of sensing a gas dissolved in a solution. The membrane includes a hydrophobic membrane layer that includes a polymeric compound that contains

fluorine wherein the hydrophobic membrane layer has a porous structure; and a pH sensitive dye embedded within the porous structure of the hydrophobic membrane layer wherein the membrane is capable of colorometrically sensing a gas.

Claim 8 recites an ammonia sensor capable of detecting gaseous phase ammonia dissolved in a solution. The ammonia sensor includes a sensing membrane that includes a hydrophobic membrane layer composed of a fluorine-containing polymeric compound wherein the hydrophobic membrane layer includes a microporous structure that has a surface defined by a number of strands within the microporous structure; and a pH sensitive dye embedded on the surface of the microporous structure of the hydrophobic membrane layer wherein the pH sensitive dye is capable of selectively reacting with the gaseous phase ammonia such that the gaseous phase ammonia is colorometrically detected.

Claim 15 recites a method of producing a membrane capable of colorometrically sensing ammonia dissolved in a solution. The method includes providing a hydrophobic membrane material that includes a polymeric compound that contains fluorine wherein the hydrophobic membrane material includes a microporous structure; providing a pH sensitive dye; and adding the pH sensitive dye within the microporous structure of the hydrophobic membrane material. The sensing membranes as claimed include a membrane and the pH sensitive dye which is intimately embedded within a microporous structure of the membrane material. In this regard, the claimed membranes can selectively detect gaseous phase constituents, such as ammonia, oxygen, carbon dioxide, the like or combinations thereof dissolved in solution. See, Specification, page 8, lines 5-11.

In contrast, the EP 045 reference fails to disclose or arguably suggest the claimed invention. For example, nowhere does the EP 045 reference disclose or arguably suggest an ammonia sensor membrane that includes a pH sensitive dye embedded within the porous structure of a membrane layer. Indeed, the Patent Office even admits that EP 045 fails to teach a pH sensitive dye embedded in this porous structure. See, Office Action, page 3. Moreover, the clear emphasis of the 045 reference relates to a layered structure wherein the membrane is coated on both sides with an excess of composition which will adhere an indicator system to the membrane of the indicator pad. See, EP 045, paragraph 28, Figure 2. For at least these reasons, clearly the EP 045 reference is distinguishable from the membrane as claimed. Therefore, Applicants respectfully submit that the EP 045 reference fails to anticipate or arguably suggest the claimed invention.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, claims 25-38 are rejected under 35 U.S.C. § 102 as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over EP 045. The Patent Office essentially asserts that the EP 045 reference, on its own, discloses or suggests the claimed invention. Applicants believe that this rejection is improper.

Of the pending claims at issue, claims 25, 26 and 34 are the sole independent claims. Claim 25 recites a method of producing ammonia sensing membrane. The method includes providing an aqueous solvent solution that contains a pH sensitive dye; providing a hydrophobic membrane that has a microporous structure; and immersing the hydrophobic membrane in the aqueous solvent such that the pH sensitive dye is embedded within the microporous structure of the hydrophobic membrane.

Claim 26 recites a method of detecting ammonia dissolved in a dialysis solution. The method includes providing an ammonia sensing membrane that is capable of detecting the ammonia wherein the sensing membrane includes a hydrophobic membrane layer that is composed of a polymeric compound that contains fluorine and a pH sensitive dye embedded within a porous structure of a hydrophobic membrane layer. The method of claim 26 further includes colorimetrically detecting a change in amount of the ammonia with the ammonia sensing membrane during dialysis therapy.

Claim 34 recites a method of providing dialysis therapy. The method includes providing an ammonia sensor that includes a sensing membrane with a hydrophobic membrane layer composed of a fluorine-containing polymeric compound and a pH sensitive dye embedded within a porous structure of a hydrophobic membrane layer, wherein the ammonia sensor is capable of colorimetrically detecting ammonia dissolved in a dialysis solution. The method further includes selectively detecting an amount of ammonia with the ammonia sensor.

As previously discussed, the membranes of the claimed invention can selectively detect gaseous phase constituents dissolved in a solution. As applied to dialysis therapy, the selective detection capabilities of the claim membranes can allow the membranes to detect varying amounts of gaseous phase constituents, such as ammonia and dialysis solution with enhanced sensitivity and responsiveness to the changes. See, Specification, page 8, lines 9-15.

In contrast, Applicants believe that the EP 045 reference, on its own, is deficient with respect to the claimed invention. As previously discussed, nowhere does the EP 045 reference disclose a membrane with a pH sensitive dye embedded within the porous structure of the

membrane as claimed and as even admitted by the Patent Office. Further, Applicants believe that this reference fails to suggest of least such features. Indeed, the clear focus of EP 045 relates to a membrane with a layered structure as discussed above. Clearly, one skilled in the art would find this structure to be distinguishable from the membranes and uses and methods of making same as required by the claimed invention.

Based on at least these differences, Applicants believe that the EP 045 reference, on its own, fails to disclose or suggest the claimed invention. Therefore, Applicants believe that the EP 045 reference fails to anticipate or render obvious the claimed invention as required by claims 25-38.

Accordingly, Applicants respectfully request that the rejection of claims 25-38 be withdrawn.

In the Office Action, claims 2, 9, 12-14, 16, 18, 19 and 26-38 are rejected under 35 U.S.C. § 103 as being unpatentable over EP 045 in view of U.S. Patent No. 4,661,246 ("Ash"). The Patent Office primarily relies on the EP 045 reference and thus relies on Ash to remedy the deficiencies of same. Applicants believe that this rejection is improper.

With respect to claims 2, 9, 12-14, 16, 18 and 19, these claims depend from a respective independent claim, namely, claim 1, claim 8 or claim 15. Thus, these claims incorporate the features of their respective independent claims as a matter of law. With respect to claims 26-38, claims 26 and 34 are the sole independent claims and recite a method of detecting ammonia and a method of providing dialysis, respectively, as discussed above.

Applicants believe that the cited art, even if combinable, is distinguishable from the claimed invention. At the outset, the EP 045 reference is deficient with respect to the claimed invention where this reference, at a minimum, fails to disclose or suggest a membrane that has a pH sensitive dye embedded within the microporous structure of the hydrophobic membrane material as required by the claimed invention. Thus, on its own, this reference is clearly deficient with respect to the claimed invention.

Further, Applicants do not believe that the Patent Office can rely solely on Ash to remedy the deficiencies of EP 045. Indeed, the Patent Office merely relies on Ash for its purported teaching regarding a dialysis instrument with a dialysate side pump for moving body fluids. Thus, Applicants do not believe that one skilled in the art would be inclined to modify the EP 045 reference in view of Ash to arrive at the claimed invention. Therefore, Applicants believe that the cited art, even if combinable, fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that the obviousness rejection with respect to claims 2, 9, 12-14, 16, 18, 19 and 26-38 be withdrawn.

In the Office Action, claim 24 is rejected under 35 U.S.C. § 103 in view of EP 045 and further in view of Werner et al. The Patent Office principally relies on the EP 045 reference and thus, it relies on the Werner et al. reference to remedy the deficiencies of same.

Applicants believe that this rejection is improper. Claim 24 recites a method of producing an ammonia sensing membrane that includes, in part, a hydrophobic membrane with a pH sensitive dye that is embedded within a microporous structure of the hydrophobic membrane. This feature, at a minimum, is clearly distinguishable from the EP 045 reference as previously discussed. Thus, on its own, the EP 045 reference is clearly deficient with respect to claim 24 based on at least these reasons.

Further, Applicants do not believe that the Patent Office can rely solely on Werner et al. to remedy the deficiencies of the EP 045 reference. Indeed, the Patent Office merely relies on Werner et al. for its alleged teachings regarding a casting technique to make a hydrophobic membrane. Thus, even if combinable, Applicants believe that the cited art fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that the obviousness rejection with respect to claim 24 be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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